Results According to the product information, an implant releases FAc for a maximum of 36 months, and an additional implant can be placed after 12 months if vision decreases or retinal thickness increases. Pivotal studies and the IRISS observational study concluded in the need to use 1.3 implants/eye and 1.13 implants/eye affected during the first 3 years respectively, this last value being the one considered by the ERG (Evidence Review Group). Taking this last reference, the cost of treatment/affected eye at € 1558.84/eye/year or € 4676.53/eye/3 years.

To estimate the target population, we used the criteria of the SMC evaluation report in which they considered a total of 179 patients with pseudophakic chronic DME eligible for treatment in the first year, increasing to 186 in the fifth year. Unlike the SMC, our NHS restricts its funding to third-line, after anti-angiogenic agents and in patients with a suboptimal response to various intravitreal dexamethasone implants or pseudophakic patients.

Making a parallelism with the Scottish population, 33.5 patients/1st year–34.8 patients/5th year would be candidates to receive FAc in our region.

NICE and the ERG found that in clinical practice 35% of patients would require bilateral treatment. Thus 12 patients/year would need treatment in both eyes in our population. The economic impact in our region would range between € 5,3000.56/year if it were inserted in only one eye and € 71,706.64/year in both eyes.

Conclusion and Relevance The financing conditions of our NHS position the drug in the third-line, which in a certain way contains the budget impact.

Since SMC restricting the conditions of use more than our NHS, the budget impact could be underestimated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-005 NEW CLOSED SYSTEM TRANSFER DEVICE CONTAINS REAL DRUG VAPOURS FOR UP TO 28 DAYS

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Background and Importance Several Closed System Transfer Devices (CSTDs) are currently approved a 7-day usage period. Increasing pressure to reduce drug costs and data supporting stability of some drugs beyond 7 days create a demand for CSTDs that contain hazardous drug vapours for 28 days. A previous study proved that a model air-cleaning CSTD contains drug vapours for 7 days.

Aim and Objectives The aim was to test drug vapour containment of an air-cleaning CSTD under extreme conditions for 28 days.

Material and Methods Cyclophosphamide (CP) was chosen as the representative drug. A model CSTD (Chemfort™) Vial Adaptor (VA) was connected to each vial, and CP was reconstituted using the CSTD Syringe Adaptor. VAs at the end of their shelf life, representing extreme conditions, were tested both immediately following and 28 days after reconstitution, with and without intact Toxi-Guard® air-cleaning systems (an integral part of the Chemfort™ VA).

Each vial was transferred to a closed test chamber connected to a vapour trap. To increase drug vapourisation, the chamber was heated to 50°C and nitrogen gas was constantly introduced into the vials. Any vapours potentially released from the Chemfort™ VA were trapped and then extracted with solvent.

Quantification of CP was performed using a validated LC/MS/MS method.

Results No CP was detected for any of the VAs with intact Toxi-Guard® components, whether tested immediately or 28 days after reconstitution, even when heat and gas flow were employed to encourage the production of vapours and when the VA was at the end of its shelf life. The limit of detection of the method was estimated at 0.02 ng. Without an intact Toxi-Guard®, 110.3 ng of CP were released into the environment.

Conclusion and Relevance The model CSTD utilising Toxi-Guard® air-cleaning technology contained drug vapours after a 28-day usage period, even under extreme conditions. A recent study proved 28-day prevention of microbial ingress by the same CSTD. Taken together, the two studies support pharmacists' decision to use drugs for their full shelf life or to extend the beyond-use-date up to 28 days when using an appropriate CSTD, thus reducing cost and waste.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

Ofer Raz and Elana Slutsky Smith are employed by Simplivia Healthcare Ltd, the manufacturer of Chemfort™. Dekel Navarro and Daniel Epstein declare no conflict of interest relating to the material presented in the abstract. Funding for this project was provided by Simplivia Healthcare Ltd, the manufacturer of Chemfort™.

2SPD-006 ARE ALL BIOLOGIC AGENTS IN THE TREATMENT OF ANKYLOSING SPONDYLITIS EQUIVALENT ALTERNATIVES?

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Background and Importance Nine drugs are currently approved for the treatment of ankylosing spondylitis (AS) in adults: adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab, secukinumab, upadacitinib and tofacitinib. Tofacitinib was the last of them to receive its approval. However, there are no direct comparisons between them.

Aim and Objectives To establish whether the drugs approved for AS in adults can be considered equivalent therapeutic alternatives (ATE) in efficacy in AS.

Material and Methods A search of clinical trials of these drugs in adult patients with AS was conducted, phase II or III, double-blinded, controlled with another drug or placebo.

Other inclusion criteria were

- Endpoint: ASAS40 (a ≥40% improvement and an absolute improvement from baseline of the Assessment in SpondyloArthritis International Society).
- Follow-up time: 12-16 weeks.

For those drugs with more than one study, a previous meta-analysis was performed using Joaquin Primo calculator. An adjusted indirect comparison (IC) of the drugs used in AS versus tofacitinib was performed using the Bucher method, using Joaquin Primo calculator. Due to lack of data in the literature and considering that therapy failure can be recovered with second lines, half of the ASAS40 value obtained in meta-analysis was taken as delta value. ATE guide was followed in order to establish a positioning.

Results

Sixteen studies were included 4 adalimumab, 2 golimumab, 1 infliximab, 1 certolizumab, 2 etanercept, 1 upadacitinib, 2 tofacitinib, 1 secukinumab and 2 ixekizumab. The difference in ASAS40 of the drugs before versus tofacitinib expressed as RAR (IC 95%) was: Adalimumab [4 (-6,1; 14,1)], certolizumab [-7,3 (-25,1; 10,5)], etanercept [2 (-11,5; 15,5)], golimumab [-5 (-16,3; 6,3)], infliximab [8,43 (-4,8; 21,6)], ixekizumab [-9 (-20, 6; 2,6)], secukinumab [-2,7 (-18,3; 12,9)], upadacitinib [-1,9 (-17,8; 13,9)]. Adalimumab, etanercept and tofacitinib are considered ATE. Infliximab, upadacitinib, secukinumab, golimumab, certolizumab, ixekizumab and tofacitinib can also be considered ATE, being the probability of clinically relevant difference <50% (most of the 95% CI is in the equivalence range) and the failure does not involve serious/irreversible damage.

Conclusion and Relevance Tofacitinib and the rest of these drugs could be considered ATE. For a definitive statement, the criteria of safety and adequacy should be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-008 BUDGETARY IMPACT DUE TO THE REPLACEMENT OF ORIGINAL LENALIDOMIDE INTO GENERIC LENALIDOMIDE

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Background and Importance The use of generic drugs is one of the most effective tools to increase efficiency in the economic management of the health system. From March 2021 to February 2022, the acquisition of the original molecule of lenalidomide (Revlimid®) represented the main expense in the ABC of drug purchases. As of this date, a generic specialty was commercialised and the Pharmacy Service proposed a replacement between them, given that both share the same indications as in the technical datasheet.

Aim and Objectives Quantifying the economic impact in the expenses of chapter II of a general hospital, caused by the acquisition of generic lenalidomide instead of Revlimid® and its repercussion on the budget during 12 months.

Material and Methods Although only two months of evolution with the new generic molecule are available, we have extrapolated this data to one year so that we can calculate the economical differences when it comes to the budget.

Results From March 2021 to February 2022, the purchase of Revlimid® has meant a net amount of € 1,014,886.46, which represents 9.8% of the total expense in chapter II (€ 10,246,115.23) and positions it as first spend in the ranking of medicines purchased in this period of 12 months.

The amount derived from the purchase of generic lenalidomide corresponding to the studied period, comes up to € 1,601.27. That results in an estimate of € 9,607.62 for 12 months.

Assuming that the same number of patients and treatments with lenalidomide were stable throughout the period, as well as the expenditure on the rest of the ABC of drugs, the economic impact generated would mean a saving of approximately € 1,005,278.84, which would cause a significant decrease in the chapter II for our Hospital (-14.25%).

Conclusion and Relevance The economic impact caused by the introduction of generic lenalidomide in our Hospital will produce savings of more than one million euros.

Speeding up the authorisation processes for generic medicines, as well as other pricing policies, are essential manoeuvres to get a cohesive health system that guarantees equal access to medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-009 AVOIDED COSTS FROM THE INCLUSION OF BREAST CANCER PATIENTS IN CLINICAL TRIALS

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Background and Importance Breast cancer is one of the tumours with the highest incidence in Spain, and its pharmacological treatment generates a huge economic impact. Clinical trials are essential for evaluating the efficacy and safety of new therapies, and also provide a financial benefit to the public health system.

Aim and Objectives The aim of this research is to calculate the saving costs in drugs, derived from the participation of breast cancer patients in clinical trials (based on the drug free support provided by the sponsor of each study).

Material and Methods A retrospective analysis was made of all breast cancer clinical trials initiated in our hospital since January 2020, and all patients included in these trials were selected. The data collected were: trial phase, investigational drug, number of subjects enrolled and number of treatment cycles received. The Oncology Department was contacted to discuss the therapeutic alternative of choice and its theoretical duration if the patient had not participated in the clinical trial. The cost of each option was calculated using the acquisition price of the drug (laboratory sale price – discount + 4% VAT). Information was obtained from the database of the clinical trials unit.

Results Since 2020, 8 breast cancer clinical trials (2 phase II and 6 phase III), were initiated in our hospital. Were included 10 subjects, receiving a total of 106 treatment cycles. The investigational medical products studied were: trastuzumab and conjugates, pertuzumab, atezolizumab, olaparib, alpelisib and palbociclib. The overall cost saving was € 198.775,32. The trial with the highest cost impact offers a saving of € 8.269,48 per cycle of each enrolled patient. The drug with highest avoided cost was pemetrexed (€ 32.890,54).

Conclusion and Relevance Clinical trials in breast cancer patients, in addition to offering the possibility of access to